PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	11.02.2005
Applicant's or agent's file reference: RLL-319WO	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 03/05877	11.12.2003	11.12.2002

Applicant
RANBAXY LABORATORIES LIMITED

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49.89 2399 - 4465	Hutterer, G Tel. +49 89 2399-8066

ENTERED

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RLL-319WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/05877	International filing date *(day/month/year)* 11.12.2003	Priority date *(day/month/year)* 11.12.2002
International Patent Classification (IPC) or both national classification and IPC A61K9/58		
Applicant RANBAXY LABORATORIES LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02.07.2004	11.02.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Giménez Miralles, J Telephone No. +49 89 2399-8655

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/05877

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-62 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 62 in respect of IA

because:

☒ the said international application, or the said claims Nos. 62 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-62
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-62
Industrial applicability (IA)	Yes:	Claims	1-61
	No:	Claims	

2. Citations and explanations

see separate sheet

Since no reply has been filed within the time limit of 3 months indicated in the Written Opinion dated 27.09.2004, the present International Preliminary Examination Report is being established on the basis of said Written Opinion (Rules 66.2(d) and 66.4*bis* PCT).

Re Item III

Present claim 62 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT, namely a method for the therapeutic treatment of the human or animal body. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of that claim (Article 34(4)(a)(i) PCT). (See Item V below).

Re Item V

1. The relevant prior art documents are referred to as D1 to D5 as in the order of appearance in the International Search Report (ISR).

2. Citations and explanations supporting the statement with regard to novelty (N), inventive step (IS) and industrial applicability (IA) (Article 33(1) PCT):

(N) The subject-matter of present claims 1-62 complies with the requirement of novelty (Article 33(2) PCT).

The prior art does not anticipate a taste masking coating composition for solid dosage forms such as granules, pellets, etc. comprising a combination of the materials i) + ii) as follows: i) a copolymer of methacrylate with quaternary ammonium groups combined with sodium carboxymethylcellulose; and ii) a polyvinyl alcohol-polyethylene glycol copolymer. It is the same for coated compositions comprising said coating; and for the methods of preparation thereof.

The document D1 (publication date 03.04.2003) is not considered to constitute prior art within the meaning of Rule 64.1 PCT for the purposes of Articles 33(2) and (3) PCT. (However, the priority right of the present international application has not been checked yet). Nevertheless, in some countries during the regional phase it may become relevant for the subject-matter of the present application.

(IS) The subject-matter of present claims 1-62 is not considered to involve an inventive step (Article 33(3) PCT) for the following reasons:

The technical problem addressed in the application is the provision of taste masking coating compositions which simultaneously allow instant release of the active agents.

D4 discloses aqueous taste masking coating compositions for solid dosage forms comprising quaternary ammonium derivatives of polymethacrylate copolymers (known as "Eudragit RL" or "RS"), which are sustained release polymers, in combination with water-soluble pore-forming polymers (disintegrants) such as carboxymethylcellulose, methylcellulose, hydroxypropylcellulose or hydroxypropylmethylcellulose (see relevant passages mentioned in the ISR). This document, therefore, can be considered as disclosing the ingredient i) of the present composition as claimed in claim 1 (see paragraph (N) above). Further, the skilled person knows in this context (general knowledge) that particularly "Eudragit RD" is a rapidly disintegrating coating suitable for taste masking consisting of a combination of a quaternary ammonium derivative of polymethacrylate copolymers and sodium carboxymethylcellulose as disintegrant. Thus, D4 can be seen as the closest prior art.

The difference of present claim 1 is that a second polymer ii) is used in combination with said ingredient i), namely a copolymer of PVA-PEG such as "Kollicoat IR". The effect achieved by said second ingredient is to increase the rate of release of the active agent. This effect, however, is not unexpected; on the contrary, it derives in an obvious manner from the known properties of "Kollicoat IR" (see D2: "Kollicoat IR" is a water-soluble film forming copolymer for instant release coatings which dissolves quickly in acidic, neutral or alkaline aqueous media). Moreover, the skilled person would be motivated by the prior art to use said "Kollicoat IR" in taste masking coating compositions (see D3: "Kollicoat IR" is useful for taste masking). Thus, when confronted with the problem of increasing the rate of release of the active agent in taste masked formulations comprising taste masking ammonium methacrylate copolymer-disintegrant coating

compositions as disclosed in D4 (e.g. "Eudragit RD" comprising sodium carboxymethylcellulose), the skilled person would be motivated to combine said first taste masking polymer with a second material such as "Kollicoat IR", because he knows from D3 that it is suitable and useful for taste masking, and knows from D2 and D3 that it is an instant release film coating which can be used as alternative to other instant release film coatings and pore-forming materials such as hydroxypropylmethylcellulose. Accordingly, the skilled person would reasonably expect that the combination of both materials i) and ii) would result in an increase of the rate of release of the active agent as compared to that observed when using the material i) alone. No other unexpected effects can be seen in the present subject-matter which could support an inventive step.

(IA) The subject-matter of present claim 1-61 is industrially applicable (Article 33(4) PCT).

For the assessment of the subject-matter of present claim 62 on the question whether it is industrially applicable (Article 33(4) PCT), no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims directed to methods for the treatment of the human or animal body by therapy; or to the use of a compound or composition in a therapeutic/medical treatment of the human or animal body; but may allow, however, claims to a known compound or composition for first use in said therapeutic/medical treatment; and the use of such a compound or composition for the manufacture of a product or medicament for a new therapeutic/medical treatment.